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18611

4482

7590

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

06/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,8,15-22,28,33,38-47,49,50,52-56,60-62 and 66-81.

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 8 April 2009, is acknowledged. Claims 15, 20, 21, 22, 39, 41, 42, 49, 50, 52, 53, 55, 56, 61 and 62 have been amended. Claim 63 has been cancelled. New claims 75-81 have been added.

Claims 1, 8, 15-22, 28, 33, 38-47, 49, 50, 52-56, 60-62 and 66-81 are pending. Claims 43-47 and 69-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 1, 8, 15-22, 28, 33, 38-42, 49, 50, 52-66, 60-62 and 66-68 and 72-81 are under consideration.

### **Rejection or Objection Withdrawn/Moot**

3. The objection to Figure 1 is withdrawn in light of the submitted replacement figure.
4. The objection to Figure 3 is withdrawn in light of the submitted replacement figure.
5. The objection to Figure 11 is withdrawn in light of the amendment of the specification and in light of the submitted replacement figure.
6. The objection to Figure 12 is withdrawn in light of the submitted replacement figure.
7. The objection to Figure 19 is withdrawn in light of the submitted replacement figure.
8. The objection to Figure 20 is in light of the submitted replacement figure.
9. The objection to Figure 21 is withdrawn in light of the submitted replacement figure.
10. The objection to claim 15 is withdrawn in light of the amendment of the claim.
11. The objection to claim 39 is withdrawn in light of the amendment of the claim.
12. The objection to claim 50 is withdrawn in light of the amendment of the claim.
13. The objection to claim 55 is withdrawn in light of the amendment of the claim.
14. The objection to claim 56 is withdrawn in light of the amendment of the claim.

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15. The rejection of claims 15-22 and 66-68 under 35 U.S.C. 112, second paragraph, indefiniteness for "characterized" is withdrawn in light of the claim amendments.

16. The rejection of claims 20, 21, 41, 42, 49, 52-56, 60-62 and 72-74 under 35 U.S.C. 112, second paragraph, indefiniteness for "derivative or equivalent" is withdrawn in light of the amendment of the claims.

17. The rejection of claim 22 under 35 U.S.C. 112, second paragraph, insufficient antecedent basis for "disease condition", is withdrawn in light of the amendment of the claim.

18. The rejection of claims 1, 8, 15-22 and 66-68 under 35 U.S.C. 112, second paragraph, indefiniteness for "effective amount" is withdrawn in light of applicant's arguments.

19. The rejection of claims 50, 52-62 and 72-74 under 35 U.S.C. 112, second paragraph, indefiniteness for "otherwise assessing" is withdrawn in light of the amendment of the claims.

#### **Rejection/Objection Maintained**

20. The objection to Figure 14 is maintained. While the submitted Figure 14 did correct the lack of "open square", the description of the figure is listed as Figure 14c, but the submitted figure is only listed as Figure 14.

21. The rejection of claims 28, 33, 38-42 and 66-68 under 35 U.S.C. 112, second paragraph, indefiniteness for "substantially" is maintained.

Applicant argues that those skilled in the art would understand the metes and bounds of the term "substantially" in light of the instant disclosure.

The examiner has considered applicant's argument, but does not find it persuasive for the reasoning put forth in the original rejection. The claims are drawn to a composition comprising a domain portion which is "substantially" incapable of inducing an immune response to a lipidic domain of a GPI. It remains unclear what are the metes and bounds of the term.

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Does it mean that the portion can or cannot induce an immune response? Does it mean that the portion produces a particular level of immune response? If so, then, what level of immune response? Thus, the term does not provide sufficient definition to determine what level of immune response is actually claimed.

### **Claim Rejections - 35 USC § 112**

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Newly added claims 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of eliciting or inducing an immune response, in a mammal, directed to a parasite wherein said mammal suffers from malaria resulting from an infection by said parasite.

It is unclear what parasites other than *Plasmodium* result in malarial infections, since the claims are drawn to any/all parasites.

### **Conclusion**

24. Claims 28, 33, 38-42, 66-68, 80 and 81 are rejected. Figure 14 is objected to.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of

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the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

June 17, 2009